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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,965	12/02/2003	Erik Buntinx	29248/18	2844

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EXAMINER	
RAMACHANDRAN, UMAMAHESWARI	
ART UNIT	**PAPER NUMBER**
1617	

MAIL DATE	DELIVERY MODE
01/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/725,965	BUNTINX, ERIK	
	Examiner	Art Unit	
	Umamaheswari Ramachandran	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41 and 42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *41 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' election of group II, claims 41-42 in the reply filed on 4/10/2007 is acknowledged. Claims 32-40, 43-77 are withdrawn from consideration. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Thus the restriction requirement elected is made final. Claims 41-42 are pending and are examined on the merits herein.

Information Disclosure Statement

The examiner notes the receipt of the IDS documents received in the office dated 8/9/2005, 4/10/2007, 8/26/2007 and 11/26/2007.

Claim Objections

Claim 41 is objected to because of the following informalities: Claim 41 depends on non-elected claim 36. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 41 and 42 rejected under 35 U.S.C. 103(a) as being unpatentable over Dudley et al. (US 2004/002482, effective filing date Mar 15 2002) in view of Squelart et al, (IDS: Applicant cited reference: Acta Psychiatr Belg, 1977, 77, 284-293), Medicaments Psychotropics (IDS: Applicant cited reference) and Coppen (U.S. 6,191,133).

Dudley et al. teach combinations and compositions for treating or preventing or reducing the risk of developing a depressive disorder or the symptoms associated with the disorder comprising compounds such as citalopram, pipamperone (see abstract, para 0132, lines 14 and 42). The reference teach that the combinations of the antidepressant agents can be used in the methods, kits, combination and compositions (para 0132, p 10, lines 5-7).

Although, Dudley et al does not explicitly teach both citalopram and pipamperone in the same composition it would have been obvious to one of ordinary skill in the art at the time of the invention to formulate a composition comprising both the compounds in the same composition because Dudley suggest the composition and combination of the compounds and further teach the compounds are useful as antidepressant agents. One of ordinary skill in the art at the time of the invention would have been motivated to formulate such a composition in expectation of success as well to achieve synergistic

and or additive benefits from deriving such a formulation as both the compounds are taught to be useful as antidepressant agents.

Dudley does not explicitly teach the dose of the antidepressant compounds in the composition.

Squelart et al. teach dosage of 80mg/day of pipamperone (Dipiperon), a neuroleptic drug to chronic schizophrenic patients (see Abstract). Medicaments Psychotropics document describe 40 mg dosages of Dipiperon, a neuroleptic (page 1).

Coppen teach treatment of depression using antidpepressive compounds like citalopram (col. 9, claims 1, 5, 6, 7). The reference teaches the daily dose of citalopram as 20-60 mg and usual tablet content to be 10, 20 mg.

It would have been obvious to one of ordinary skill in the art at the time of the invention to formulate a pharmaceutical composition comprising a compound having (i) a selective affinity for the Dopamine-4 (D4) receptor with a pKi value equal to or higher than 8 towards the D4 receptor and less than 8 towards other Dopamine receptors, and (ii) a selective affinity for the 5-HT2A receptor with a pKi value equal to or higher than 8 towards the 5-HT2A receptor and less than 8 towards other 5HT receptors such as pipamperone (b) a selective serotonin re-uptake inhibitor, citalopram because Dudley teach both the compounds to be antidepressants, Squelart teach pipamperone as a neuroleptic drug in the treatment of chronic schizophrenic patients and Coppen teach citalopram useful in the treatment of depression. One of ordinary skill in the art would have been motivated to incorporate the agents herein in a single combination pharmaceutical composition because combining the agents herein each of which is

known to be useful to treat mental disorders including depression individually into a single composition useful for the very same purpose is *prima facie* obvious. See *In re Kerkhoven* 205 USPQ 1069.

It would have been obvious to one of ordinary skill in the art at the time of the invention to formulate a composition comprising such compounds in an amount range as claimed in claim 42 because Squelart teach 80 mg/daily dose and Medicaments Psychotropics teach 40 mg doses of pipamperone and Coppen teach daily dose of citalopram as 20-60 mg and usual tablet content to be 10, 20 mg. Also, the amount of an ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Conclusion

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Umamaheswari Ramachandran whose telephone number is 571-272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER